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08/485,438	06/07/95	EISENBERG	S 65850-1103.2

EXAMINER	
MOORE, W	

ART UNIT	PAPER NUMBER
1814	7

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DATE MAILED: 06/26/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire Three (3) month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1 through 11 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1 through 11 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Two of the co-inventors named in the instant Continuation-In-Part application and in the parent applications serial numbers 07/943,369 and 08/209,040, filed respectively September 9, 1992, and March 9, 1994, are also co-inventors in the copending, commonly-assigned, applications serial numbers 07/712,354 and 08/279,065. One co-inventor herein is also a co-inventor of U.S. Patent No. 4,760,130. Yet applicant's Declaration in the instant application makes no claim for the benefit of priority of these earlier-filed U.S. patent applications. Rejections under 35 U.S.C. §112, first paragraph, stated in the parent application and a parallel co-pending Continuation-In-Part application are not applicable to the claims pending herein drawn to CLPI products because they can readily be made by skilled artisans and are enabled for use in processes that are practicable, e.g., topical administration in the human respiratory tract to inhibit secreted serine proteases, irrespective of the instant disclosure. A Notice of Draftsman's Patent Drawing Review, stating informalities requiring correction, accompanies this communication.

Full compliance with 37 CFR 1.821 is required in response to this Office action. Applicant's submission of a Sequence Disclosure in Computer Readable Form [CRF] by requesting conversion of the CRF of the parent application into the CRF for the instant application, Paper No. 5 filed June 5, 1996, brings the application partially into compliance. No sequence listing in printed form was submitted, however, together with instructions directing its entry as an amendment to the specification, e.g., entry as pages 38 and 39 of the specification together with the renumbering of the current pages 38 and 39 as pages 40 and 41.

The disclosure is objected to because of the following informalities:

The term "PEGylated" at lines 15 and 17 of page 7 is undefined. No results are presented to support the conclusion of Example 3, lines 21-24, at page 14. The citation of Kramps et al. at lines 14 and 15 of page 12 is incomplete as no date is stated. No conjunction is present at page 27, line 14, following "U937 cells".

Appropriate correction is required.

Claims 3 and 9 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amino acid sequences recited in claims 3 and 9 are ambiguous in stating a position "R9" after "R8 R3" but not identifying any substituents for "R9" in the following clauses; either the native CLPI amino acid at position 27 should be stated or a range of substituents should be recited at that position.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. §102(b) as being clearly anticipated by Thompson et al.('497). An isolated serine protease inhibitor ihibiting chymotrypsin and elastase but not trypsin remains anticipated by any other inhibitor that has the same characteristics. Thompson et al.('497) disclose, see page 12, SLPI analogs that inhibit chymotrypsin and elastase but not trypsin and claim, see claims 10 and 16-18, SLPI analogs having phenylalanine, glycine or valine as substituents at position 72, or "R8" that meet the limitations describing the inhibitor of claim 1.

Claim 1 is rejected under 35 U.S.C. §102(b) as being clearly anticipated by Thompson et al.('130). An isolated serine protease inhibitor that inhibits chymotrypsin and elastase but not trypsin remains anticipated by any other inhibitor that has the same characteristics. Thompson et al.('130) disclose, see col. 8, SLPI analogs that inhibit chymotrypsin and elastase but not trypsin and disclose and claim, claims 1 and 6-8, SLPI analogs having phenylalanine, glycine or valine as substituents at position 72, or "R8" that meet the limitations describing the inhibitor of claim 1.

Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. §102(b) as being clearly anticipated by Stetler et al. An isolated CLPI or CLPI analog and a polynucleotide segment encoding a CLPI or analog remains anticipated by any other similarly-described CLPI or CLPI analog. Stetler et al. disclose, see pages 58-59, designing a polynucleotide segment encoding CLPI and an expression vector for the recombinant expression of CLPI, which inhibits chymotrypsin and elastase but not trypsin and has the amino acid sequence of the instant claim 2, thus inherently disclose a polynucleotide segment encoding the CLPI of claim 8.

Claims 1 and 7 are rejected under 35 U.S.C. §102(b) as being clearly anticipated by Bandyopadhyay et al. An isolated serine protease inhibitor ihibiting chymotrypsin and elastase but not trypsin remains anticipated by any other inhibitor that has the same characteristics. The SPLI analog disclosed at pages 13 and 14 of Bandyopadhyay et al. meets the limitations describing the inhibitor of claim 1. Bandyopadhyay et al. further disclose, pages 31-54, the design and preparation of polynucleotide segments encoding SLPI and SLPI analogs and the preparation of expression vectors for their recombinant production, thus disclosing the polynucleotide segment encoding the inhibitor of claim 7.

Claims 1-3 and 7-11 are provisionally rejected under 35 U.S.C. §102(e) as being anticipated by copending application serial No. 08/279,056. Copending application serial No. 08/279,056 has a common assignee as well as two common co-inventors with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. §102(e) if patented. This provisional rejection under 35 U.S.C. §102(e) is based upon a presumption of future patenting of the conflicting copending application.

Claims 1-11 are provisionally rejected under 35 U.S.C. §102(e) as being anticipated by copending application serial No. 07/712,354. Copending application serial No. 07/712,354 has a common assignee as well as two common co-inventors with the instant application. Based upon the earlier effective U.S. filing date of the copending application,

it would constitute prior art under 35 U.S.C. §102(e) if patented. This provisional rejection under 35 U.S.C. §102(e) is based upon a presumption of future patenting of the conflicting copending application.

Either of these provisional rejections under section 102(e) might be overcome either by a showing under 37 CFR 1.132 that any unclaimed invention disclosed in the copending applications was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention of any claimed subject matter prior to the effective U.S. filing date of the copending application.

Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-24, 31-33, 35-40, 42-44, 52 and 53 of copending application Serial No. 07/712,354. Although the conflicting claims are not identical, they are not patentably distinct from each other because the capacity for substitutions from among the same set of amino acids in CLPI at positions R3-R9 is identical for the affected claims of both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application of patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

The prior art made of record, Thompson et al.(1986), Smith et al., Heinzel et al., Rubin et al., Webb et al., Glover et al.('019), Tollefsen et al., Marganore et al., Insley et al., Lucey et al., Birrer et al., Kramps et al., Bohm et al. and Hirsch, and not relied upon is considered pertinent to applicants disclosure.

The teaching of Thompson et al.(1986) corresponds to Thompson et al.('130) and the teachings of Smith et al., Heinzel et al., Rubin et al., Webb et al., Glover et al.('019), Tollefsen et al., Marganore et al., Insley et al., Hirsch, Lucey et al. and Birrer et al. were cited in the parent application. Kramps et al. and Bohm et al. teach, respectively, the localization of inhibitory function in the carboxyl-terminal domain of SLPI and a further tissue source of native SLPI.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in

Crystal Mall 1 (CM1). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4227 and (307) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is (703) 308-0583. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

William W. Moore
June 18, 1996

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180